§ 514.11 Confidentiality of data and information in a new animal drug application file.

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(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before the application has been approved, unless it has been previously disclosed or acknowledged.

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(d) If the existence of an NADA file has been publicly disclosed or acknowledged before the application has been approved, no data or information contained in the file is available for public disclosure, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, i.e., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an application has been approved, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

* * * * *

(2) * * *

(ii) For an NADA approved after July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the application is approved.

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§ 514.12 Confidentiality of data and information in an investigational new animal drug notice.

(a) The existence of an INAD notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an INAD file shall be handled in accordance with provisions established in § 514.11.

§ 514.15 Untrue statements in applications.

Among the reasons why an application for a new animal drug or animal feed bearing or containing a new animal drug may contain an untrue statement of a material fact are:

(a) Differences in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the product from the conditions of such use stated in the application;

(2) Articles used as components of the product from those listed in the application;

(3) Composition of the product from that stated in the application;

(4) Methods used in or the facilities and controls used for the manufacture, processing, or packing of the product from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application; or

(b) The unexplained omission in whole or in part from an application or from an amendment or supplement to an application or from any record or report required under the provisions of section 512 of the act and § 514.80 or § 510.301 of this chapter of any information obtained from:

(1) Investigations as to the safety, effectiveness, identity, strength, quality, or purity of the drug, made by the applicant on the drug, or

(2) Investigations or experience with the product that is the subject of the application, or any related product, available to the applicant from any source if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality, or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the product.

(c) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, and the application fails to include a brief statement of the reason for the noncompliance.

[40 FR 13825, Mar. 27, 1975, as amended at 49 FR 7226, Feb. 28, 1984; 50 FR 7517, Feb. 22, 1985; 68 FR 15365, Mar. 31, 2003]

Subpart B—Administrative Actions on Applications